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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,675	05/22/2006	Shabnam Tangri		8341

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SHABNAM TANGRI
5683 GLENSTONE WAY
SAN DIEGO, CA 92121

EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

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06/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,675	TANGRI ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *27-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 27 a, c-j, o, q-x 28, 29, 30, 33, drawn in part to a composition comprising a modified erythropoietin construct (MEC) polypeptide, nucleic acid, vector, host cell, method of administering an EPO, a method of producing and isolating a recombinant peptide/polypeptide/protein and EPO SEQ ID NOs:10-14, 20-50, 152-247.

Group II, claim(s) 27 g, h, i, j, 29, 30 and 33, drawn in part to a composition comprising a calcitonin sequence comprising SEQ ID NOs:51-56 and a method of producing and isolating a recombinant peptide/polypeptide/protein.

Group III, claim(s) 27 g, h, i, j, 29, 30 and 33, drawn in part to a composition comprising a hGH sequence comprising SEQ ID NOs:57-82 and a method of producing and isolating a recombinant peptide/polypeptide/protein.

Group IV, claim(s) 27 g, h, i, j, 29, 30 and 33, drawn in part to a composition comprising an IFNb sequence comprising SEQ ID NOs:83-113 and a method of producing and isolating a recombinant peptide/polypeptide/protein.

Group V, claim(s) 27 g, h, i, j, 29, 30 and 33, drawn in part to a composition comprising an insulin sequence comprising SEQ ID NOs:114-122 and a method of producing and isolating a recombinant peptide/polypeptide/protein.

Group VI, claim(s) 27 a, b, c, d, e, f, m-x, 29 and 30, drawn in part to a composition comprising a MEC and further comprising a heterologous polypeptide sequence, carrier, nucleic acid, vector, host cell, EPO SEQ ID NOs:10-14, 20-50, 152-247 and a method of producing and isolating a recombinant peptide/polypeptide/protein.

Group VII, claim(s) 27 k, l, m, q, 29 and 30, drawn in part to a composition comprising a polypeptide/peptide/protein, carrier, nucleic acid, vector and host cell and a method of producing and isolating a recombinant peptide/polypeptide/protein.

Group VIII, claim(s) 27 r-u, 29 and 30, drawn in part to the nucleic acid, vector and host cell and a method of producing and isolating a recombinant peptide/polypeptide/protein as recited in claim 27m.

Group IX, claim(s) 28, drawn in part to a method of administering a calcitonin sequence comprising SEQ ID NOs:51-56.

Group X, claim(s) 28, drawn in part to a method of administering a hGH sequence comprising SEQ ID NOs:57-82.

Group XI, claim(s) 28, drawn in part to a method of administering a IFNb sequence comprising SEQ ID NOs:83-113.

Group XII, claim(s) 28, drawn in part to a method of administering a insulin sequence comprising SEQ ID NOs:114-122.

Group XIII, claim(s) 27 k, l, m, n, q, r, drawn in part a composition comprising an antibody.

Group XIV, claim(s) 29 and 30, drawn in part to a method for producing and isolating a recombinant antibody.

Group XV, claim(s) 31 and 32, drawn to a method for reducing a helper T lymphocyte (HTL) response against a candidate protein.

The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups IX-XII, XIV and XV are directed to unrelated methods. Groups IX-XII, XIV, XV recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. The special technical feature of Groups IX-XII is a method of administering a calcitonin sequence, a hGH sequence, an IFNb sequence or

an insulin sequence, respectively. The special technical feature of Group XIV is a method for producing and isolating a recombinant antibody. The special technical feature of Group XV is a method for reducing a helper T lymphocyte (HTL) response against a candidate protein. A search to identify documents relevant to the patentability of the claimed methods of would not necessarily employ the same or similar search terms and techniques. Each method has acquired a separate status would require its own search of the literature databases. Thus, a search and examination of all methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive and/or the subject matter is divergent.

Groups I-VIII and XIII are directed to unrelated products. Groups I-VIII and XIII are directed to distinct compositions, are not required one for the other, and/or achieve different goals. The polypeptides of Groups I-VIII may be used in far-western assays or to make antibodies, while the antibodies of Group XIII cannot. In addition, the products of Groups I-VIII all comprises diverse sequences and recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Furthermore, searching the inventions of Groups I-VIII would impose a serious search burden since a search of one sequence would not be used to determine the patentability of another sequence from the Groups. Each sequence requires its own search of the sequence and literature databases.

Inventions II/IX, III/X, IV/XI and V/XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Groups I-VIII can be used in can be used in a materially different process such as methods to make antibodies, methods to make recombinant proteins and far-western assays.

Inventions XIV and XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody product can be made by another and materially different process, such as inoculating animals and isolating the antisera.

Inventions are unrelated. Inventions I/IX-XII, XIV, XV; II/X-XII, XIV, XV; III/IX, XI, XII, XIV, XV; IV/IX, X, XII, XIV, XV; V/IX-XI, XIV, XV; VI-VIII/IX-XII, XIV, XV and XIII/IX-XII, XV are unrelated because the product is not used or otherwise involved in the process.

Accordingly, Groups are not so linked by the same or corresponding feature as to form a single inventive concept. A search and examination of the methods in one patent application would result in an undue burden, since the methods are not co-extensive, the classification is different, and/or the subject matter is divergent. Furthermore, PCT practices do not provide for examination of multiple methods of using the first claimed product.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. SEQ ID NOs:10-14, 20-50, 152-247
2. SEQ ID NOs:51-56
3. SEQ ID NOs:57-82
4. SEQ ID NOs:83-113
5. SEQ ID NOs:114-122
6. proteins recited in claim 27m

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species comprise distinct sequences because they are composed of unrelated or diverse sequences, different coding regions and/or imparts structural and functional differences. Each sequence represents a separate contribution to the art.

Applicant is required, in reply to this action, to elect 5 species to which the claims shall be restricted if no generic claim is finally held to be allowable. That is to say, depending on the elected Group, Applicant is required to elect 5 SEQ ID NOs or 5 proteins. For example, if Group I is elected, Applicant is required to elect 5 SEQ ID NOs out SEQ ID NOs:10-14, 20-50, 152-247. If Group III is elected, Applicant is required to elect 5 SEQ ID NOs out of SEQ ID NOs:57-82. If Group VII is elected, Applicant is

required to elect 5 protein species as recited in claim 27m. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
6/19/08

/Manjunath N. Rao, /
Supervisory Patent Examiner, Art Unit 1647